DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 14, 2015

T.A.G Medical Products Corporation, Ltd.
c/o Mr. George J. Hattub
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K143326
Trade/Device Name: T.A.G. Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant and Abutments
Regulatory Class: II
Product Code: DZE, NHA
Dated: January 28, 2015
Received: February 4, 2015

Dear Mr. Hattub:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143326

Device Name: T.A.G. Dental Implant System

Indications For Use: The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K143326

510(k) Summary

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a)	**Submitter Address:**	George J. Hattub MedicSense, USA 291 Hillside Avenue Somerset, MA 02726 www.medicsense.com
1. (b)	***Manufacturer Address:***	T.A.G. Medical Products D. N. Ashrat Kibbutz Gaaton 25130, Israel
	Mfg. Phone:	Tel.: 972-3-647-4840
	Contact Person:	Erez Adiv
	Date:	May 6, 2015
2.	***Device & Classification***	Endosseous Dental Implant & Abutments- class II device (product codes: DZE & NHA). 21 CFR 872.3640
	Name:	T.A.G. Dental Implant System
3.	***Predicate Devices:***	MIS Dental Implant System (K040807), AB Dental Implants and Accessories (K112440) & MIS UNO Narrow Implant System (K092555)
4.	***Description:***	The T.A.G.'s Dental Implant System is composed of three sub-families:

(1) Massif - A self-tapping cylindrical screw type implant
Available in lengths: 8 - 16 mm and diameters: 3.75 - 6.0 mm
Note: length 6 mm not available for diameters below 4.2 mm.

(2) Axis - A self-tapping conical implant.
Available in lengths: 8 - 16 mm and diameters: 3.75 - 6.0 mm
Note: length 8 mm not available for diameters below 3.75 mm, length 16 mm not available for diameters above 4.2

(3) Crestone - A one piece implant
Available in Lengths of 10 - 16 mm and Diameters 3.0 - 3.5 mm.

The implants are provided sterilize for single patient use.

Each implant is provided with cover screw inside the sterile package.

All implants are made of titanium alloy grade 23 (Ti-6Al-4V-ELI).

Provided are accessories which are used in dental implantation procedures.

They are:
Superstructures which are Healing Caps & Abutments made from Titanium Alloy TI 6AL 4V ELI, Stainless Steel, and/or PEEK. The superstructures are single patient use to be supplied non-sterile.

5. ***Intended Use:*** The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

6. ***Comparison of Technological Characteristics:*** With respect to its indication for use, the T.A.G. Dental Implant System is substantially equivalent to its predicate devices in that it intended for the same clinical purpose. With respect to technology, the design is similar as confirmed by comparison, and the performance is the same as verified by validation. Based upon this, T.A.G. Medical Products believes that its device is substantially equivalent to its predicate devices.

Please see comparison table on next page.

Feature	T.A.G. "Massif"	AB Dental "I2" Screw Type Implant	T.A.G. "Axis"	MIS Dental Implants "SEVEN"	T.A.G. "Crestone"	MIS UNO Dental Implants
Intended Use	The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	AB Dental Implants are intended for surgical placement in the maxillary and/or the mandibular arch to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. 17 Integral Implant, 15 Conical Implant, P15 Temporary Abutment, P12-T, L Temporary Flat Connection Abutment and P 16 Straight Adapter are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	**MIS** dental implants are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore a patient's chewing function.	The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading	The UNO Narrow Implant is indicated for use in surgical and restorative applications for placement in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws where the horizontal space is limited by adjacent teeth and roots, to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function. Mandibular central and lateral incisors must be splinted if using two or more 3.0 mm implants adjacent to one another. The UNO Narrow Implant is indicated for immediate implantation in extraction sites or implantation in partially healed or completely healed alveolar ridge situations. When a one stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.
Implant Material	Ti6AL4V ELI	same	same	same	same	same
Implant Dimensions	Dia.3.75 - 6mm L =8-16mm	Dia.3.3 - 6mm L =6-16mm	Dia.3.3 - 6mm L =8-16mm	Dia. 3.3-6mm L=6-16mm	Dia.3.0 - 3.5mm L =10 - 16mm	Dia. 3.0-3.5mm L= 10-16 mm
Implant Surface	Sand blasting/ acid etching	Sand blasting/ acid etching	Sand blasting/ acid etching	Sand blasting/ acid etching	Sand blasting/ acid etching	Sand blasting/ acid etching
Implant Design Shape	Cylinder screw	Cylinder screw	Conical screw	Conical screw	One - piece	One Piece

Feature	T.A.G. "Massif"	AB Dental "I2" Screw Type Implant	T.A.G. "Axis"	MIS Dental Implants "SEVEN"	T.A.G. "Crestone"	MIS UNO Dental Implants
Sterility of Implant	Gamma	Gamma	Gamma	Gamma	Gamma	Gamma

Feature	T.A.G. "Massif"	AB Dental "I2" Screw Type Implant	T.A.G. "Axis"	MIS Dental Implants "SEVEN"	T.A.G. "Crestone"	MIS UNO Dental Implants
Abutment Design	Straight and up to 25 degrees	Straight and up to 25 degrees	same	Straight and up to 20 degrees	NA	NA
Abutment Material	Stainless Steel, Titanium, and/or PEEK	Titanium and/or Plastic	same	Titanium and/or Plastic	NA	NA
Abutment Length	4-8 mm	1-9 mm	same	1-9 mm	NA	NA
Sterility of Abutment	Non sterile	Non sterile	Non sterile	Non sterile	NA	NA
510(k) #	pending	K112440	pending	K040807	pending	K092555

7. ***Discussion of Testing Submitted:***

No clinical testing was submitted for this 510(k) notification. Performance testing, which was submitted, was performed at an accredited independent laboratory in accordance with FDA's **Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments - Guidance for Industry and FDA Staff** and **ISO14801 Static and Cycling Loading Test of Dental Implants.** This results of this testing demonstrated that T.A.G. Dental Implant System meets the requirements of the standards.

8. ***Conclusions Drawn:***

Based upon the descriptive information provided in this 510(k) notification as well as the test results of the performance testing submitted, the T.A.G. Dental Implant System function in a substantially equivalent manner and do not raise additional safety issues. As such, the T.A.G. Dental Implant System is substantially equivalent to its predicate devices.